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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,275	08/01/2005	Wei-Ping Min	4767-217 LAB	9949

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SIM & MCBURNEY
330 UNIVERSITY AVENUE
6TH FLOOR
TORONTO, ON M5G 1R7
CANADA

EXAMINER	
HAMA, JOANNE	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/517,275	MIN ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-54* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This Application is a 371 of PCT/CA03/00867, filed June 10, 2003, and claims priority to foreign application 2,388,411, filed June 10, 2002, in Canada.

Amendment to the claims was filed December 9, 2004.

Claims 1-54 are pending.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-46, 48-52, 54, drawn to a mammalian immune cell exhibiting a targeted endogenous gene-specific knockout phenotype and to a medicament and composition comprising the cell, a method for making an immune cell that alters the activity of a T cell *in vivo*, wherein the immune cell is transformed *in vitro* with at least one construct that inhibits the expression of an endogenous target gene and a method for the treatment of autoimmune disorders and transplantation rejection in a mammalian subject, wherein a therapeutically effective amount of a composition is administered to a subject, wherein the composition comprises DC that contain at least one construct that inhibits the expression of an endogenous target gene.

Group 2, claim(s) 22, 24, 27, 32, 33, 38, 39, 41-45, 47, 48 drawn to a medicament comprising siRNA or hybrid DNA/RNA and to a method of decreasing the immunogentic and rejection potential of an organ for transplantation and a method of decreasing the immunogenicity and rejection potential of an organ for transplantation.

Group 3, claim(s) 53, 54, drawn to a method for the treatment of autoimmune disorders and transplantation rejection in a mammalian subject, wherein a therapeutically effective amount of a composition is administered to a subject, wherein the composition comprises an siRNA targeted to inhibit an endogenous gene in an antigen presenting cell.

The inventions listed as Groups 1-3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of invention between different catagories of inventions will only be found to exist if the specific combinations are present. These combinations include:

1) a product and special process of manufacture of said product,

2) a product and a process of use of said product,

3) a product, a special process of manufacture of said product, and a process of use of said product,

4) a process and an apparatus specially designed to carry out said process,

5) a product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said product, and methods of making multiple products as claimed in the instant application, see MPEP § 1850. The groups do not share a special technical feature because at the time of filing, Li et al., 1999, Nature Medicine, 5: 1298-1302, teach that IL-2 knockout mice exhibit profound defects in activation-induced T-cell apoptosis (Li et al., page 1298, 1st col., 1st parag. of Introduction).

While Groups 1-3 are similarly drawn to immune cells, nucleic acids used to manipulate the immune cells and methods of manipulating the immune cells, Group 1 is distinct from Group 2 because Group 1 is drawn to cells and method of using the cells, while Group 2 is drawn to siRNA or hybrid DNA/RNA (nucleic acids) and to the method

of using them. Group 3 is distinct from Group 1 because while Group 1 similarly has a method of treating autoimmune disorders and transplant rejection, the steps for carrying out the method are distinct between the two. Group 1 requires the use of a dendritic cell while Group 3 requires the use of siRNA. These are two structurally and functionally distinct products and the methods of using them are different. Group 3 is distinct from Group 2 because the final results of the method following administration of siRNA are different between the two groups. Decreasing immunogenicity is one way reducing the symptoms of an autoimmune disorder or reduces the chance of an organ rejection, however, it does not treat the disorder or potential for organ rejection, which is the goal of Group 3. The search and examination for each of these groups are burdensome because the searches are not coextensive.

The claims are further restricted as follows:

Should Group 1 be elected, immune cells comprising siRNA and hybrid DNA/RNA as listed in claims 3, 33, 48, and 52 are distinct inventions and one must be elected. The inventions are distinct from each other because each has a different structure and each has a different biological activity. The search and examination of both constructs is burdensome because the searches are not coextensive.

Should Group 1 be elected, immune cells comprising constructs that inhibit specific categories of endogenous genes, as listed in claims 4, 21, and 32, are distinct inventions and one must be elected. The inventions are distinct from each other because each has a distinct biological activity. The search and examination for each of

these categories of endogenous gene are burdensome because the searches are not coextensive.

Should Group 2 be elected, an siRNA possessing specific homology to part or the entire exon region of a gene of distinctly named specific categories of endogenous genes, as listed in claims 22 and 32, are distinct inventions and one must be elected. The inventions are distinct from each other because each has a different biological activity in the cell. The search and examination of each category of endogenous genes is burdensome because the searches are not coextensive.

Should Group 2 be elected, specifically named constructs of siRNA and hybrid DNA/RNA, as listed in claims 33, 48 are distinct inventions and one must be elected. Each of the constructs is distinct from the other because each has a different structure and is involved in different biological activities. The search and examination for each of the constructs is burdensome because the searches are not coextensive.

Should Group 3 be elected, specifically named categories of endogenous genes that are targeted by siRNA, as listed in claim 53, are distinct inventions and one must be elected. The inventions are distinct from each other because each has a distinct biological activity. The search and examination for each of these categories of endogenous genes are burdensome because the searches are not coextensive.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claims 5, 6, 28, 29, 34, 35 of Group 1 are drawn to specifically named "antigen presenting cells" and one or a specifically named mixture must be elected. The cells are distinct from each other because each has a distinct structure and distinct function. The search and examination for each of these cell types are burdensome because the searches are not coextensive.

Claims 12, 13, 15, 23, 25, 41, 42, and 43 of Group 1 are drawn to specifically named target genes and one must be elected. Each of the genes is distinct from each other because they encode proteins, each of which has a distinct structure and function. The search and examination of each targeted gene is burdensome because the searches are not coextensive.

Claims 18, 27, and 44 of Group 1 are drawn to specifically named disorders that are treated by the administered immune cell and one must be elected. Each disorder is distinct from the other because each has a different etiology and pathology. The search and examination of each disorder is burdensome because the searches are not coextensive.

Claims 23 and 25 of Group 1 are drawn to specifically named antigens, and one must be elected. Each of the antigens is distinct from each other because each comprises a distinct structure and each has a different biological activity from the other. The search and examination for each of the antigens is burdensome because the searches are not coextensive.

Claims 27 and 44 of Group 2 are drawn to specifically named immune disorders and one must be elected. Each of the disorders is distinct because each has its own etiology and pathology. The search and examination for each disorder is burdensome because the searches are not coextensive.

Claims 41, 42, 43 of Group 2 comprise specifically named endogenous target genes and one must be elected. Each of the target genes encodes proteins, each of which has a distinct biological function. The search and examination for each target gene is burdensome because the searches are not coextensive.

Claim 54 of Group 3 comprises distinctly named autoimmune disorders and one must be elected. Each of the disorders is distinct from the other because each has its own etiology and pathology. The search and examination for each of the categories is burdensome because the searches are not coextensive.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic:

Claims 1-6, 9, 10, 12-29, 32-35, 38, 39, 41-45, 50, 54 of Group 1 are generic for antigen presenting cells.

Claims 1-46, 48-52, 54 of Group 1 are generic for specifically named target genes.

Claims 1-46, 48-52, 54 of Group 1 are generic for specifically named disorders.

Claims 1-46, 48-52, 54 of Group 1 are generic for specifically named antigens.

Claims 22, 24, 27, 32, 33, 38, 39, 41-45, 47, 48 of Group 2 are generic for specifically named disorders.

Claims 22, 24, 27, 32, 33, 38, 39, 41-45, 47, 48 of Group 2 are generic for specifically named endogenous target genes.

Claims 53 and 54 of Group 3 are generic for autoimmune disorders.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER